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TITLE: Integrating Traumatic Brain Injury Model Systems Data into the Federal Interagency Traumatic Brain Injury Research Informatics Systems

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14. ABSTRACT

The project has successfully completed the ultimate objective of this project to incorporate data from the Traumatic Brain Injury Model Systems (TBIMS) into the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. Data on 14,159 unique TBIMS cases and 40,245 follow-up assessments collected at 1, 2, 5, 10, 15, 20, and 25 years post-injury were submitted to FITBIR using 15 separate forms which included between 17 and 137 individual data elements. In total, 12,908,949 separate data elements were submitted on 257,990 forms, which represents the largest contribution of data to FITBIR. All project aims have been successfully completed including evaluating the compatibility of the data sharing policies between the TBIMS and FITBIR, developing crosswalks between the TBIMS data and FITBIR common data elements (CDEs), developing forms for transferring TBIMS unique data elements (UDEs) to FITBIR, testing the data submission process, pilot testing the adoption of Global Unique Identifiers (GUIDs), and pilot testing the addition of new CDEs into the TBIMS data. After reviewing the results of these efforts, the TBIMS Project Directors voted to adopt the GUID and transfer TBIMS data to FITBIR on an ongoing basis, but rejected adding any new CDEs to the TBIMS National Database.

15. SUBJECT TERMS
Traumatic brain injury (TBI); TBI Model System National Database

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1. INTRODUCTION:

Since 1989, the Traumatic Brain Injury (TBI) Model System (TBIMS) Program has enrolled over 15,000 adults with moderate to severe TBI in a National Database (NDB) and collected longitudinal follow-up data at 1, 2, 5, 10, 15, 20, and 25 years post injury. The Federal Interagency TBI Research (FITBIR) Informatics System has been established to accelerate TBI research by operationalizing precise definitions of common data elements (CDEs) selected for consistent use in TBI research, and to serve as a repository for housing CDEs and other variables collected across the many TBI research studies. The ultimate objective of this project is to incorporate data from the TBIMS NDB into FITBIR for easy access and linking to other TBI studies by the TBI research community.

2. KEYWORDS:

Traumatic brain injury (TBI); TBI Model System National Database; FITBIR

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major aims of this project were to evaluate: 1) the compatibility of the data sharing policies and procedures between the TBIMS and FITBIR, 2) the exact crosswalk between the TBIMS NDB and the TBI CDEs implemented by FITBIR, 3) the degree to which TBIMS variables can be converted to FITBIR CDEs, aliases, and new data elements, and these variables formatted in existing published or new FITBIR data forms, 4) the feasibility of downloading a de-identified version of the current TBIMS NDB to FITBIR, 5) the feasibility of adding the FITBIR Global Unique Identifier (GUID) over time as new and existing patients are contacted for data collection, and 6) the feasibility of prospectively collecting more CDEs that are not currently variables in the TBIMS NDB by a sample of current TBI Model Systems.

What was accomplished under these goals?

The ultimate objective of this project to incorporate data from the TBIMS NDB into FITBIR for easy access and linking to other TBI studies by the TBI research community was accomplished in the last project quarter. As part of Aim 4 above, data on the initial acute care and rehabilitation of 14,159 unique TBIMS cases (with moderate to severe TBI) were submitted to FITBIR. Data on 40,245 follow-up assessments collected at 1, 2, 5, 10, 15, 20, and 25 years post-injury were also submitted. The TBIMS data were submitted to FITBIR using 15 separate forms which included between 17 and 137 individual data elements. In total, 12,908,949 separate data elements were submitted on 257,990 forms, which represents the largest contribution of TBI data to FITBIR (see Appendix B for more detail on this submission).

The TBIMS policy was modified to allow submission of TBIMS data to FITBIR through the adoption of Standard Operating Procedure (SOP) 602e “Submission of TBIMS Data to FITBIR” (see Appendix C). SOP 602e was an effort to balance the responsibility and benefits of contributing TBIMS data to FITBIR for increased availability to other TBI researchers, with the appropriate desire of TBIMS researchers to have the first opportunity to analyze and publish TBIMS data. Key elements of the SOP include: (1) delaying the submission of TBIMS data two years before submission to FITBIR, which is consistent with the NIDILRR policy on data sharing, (2) converting all compatible TBIMS NDB variables to common data element (CDE) formats when possible, and submitting non-compatible TBIMS variables as unique data elements (UDEs), (3) submitting TBIMS data to FITBIR on an annual basis, (4) limiting the submission of TBIMS data to the NDB core Form I and Form II variables, excluding module data, (5) fully deidentifying all data submitted, including deleting center identifiers and changing dates to age at injury and time post injury, (6) not submitting any data on any participant that refused to provide personal information to create a GUID or refused to have their data

submitted to FITBIR, (7) actively encouraging researchers to collaborate with the TBIMS when using TBIMS data, and (8) maintaining the current policy of releasing the latest TBIMS data to researchers who request data directly from the TBIMS through SOP 602b.

To summarize regulatory approval to date on this pilot project, local IRB and HRPO approval was obtained for the TBIMS National Data and Statistical Center (NDSC), all 16 TBIMS Centers, and a follow-up center. The fact that this approval process took over a year to complete contributed to the delays experienced in this project.

The review of TBIMS and FITBIR data sharing policies was completed and discussed with the TBIMS Project Directors (Aim 1). Crosswalks were identified for all TBIMS common data element (CDE) variables to be entered into FITBIR (Aim 2). Forms for submitting the unique data element (UDE) variables were designed and approved by FITBIR (Aim 3).

The pilot test of using GUIDs (Aim 5) was completed at all TBIMS centers. Centers (1) gained the consent of TBIMS participants to have their data submitted to FITBIR, (2) collected personal identifying information (PII), (3) used the PII to create GUIDs, and (4) submitted the GUIDs to the TBI NDB. Sixteen centers participated with a total of 1,689 TBIMS individuals consenting and their GUIDS entered into the NDB. The GUID process will continue at all centers since the Project Directors voted to continue GUID data collection after review of the GUID Pilot results (see Appendix D). Data Collectors, Data Managers, and Project Directors at local centers are applying for annual extensions of their FITBIR accounts to maintain access to the GUID Tool.

The pilot test of adding CDEs to the TBIMS NDB (Aim 6) is now complete at all centers. Core TBI CDEs were selected for addition to the TBIMS Form I and II. New Form I CDEs include type of TBI, duration of loss of consciousness (LOC) and post-traumatic amnesia (PTA), years of education, and status of school attendance and current employment. New Form II CDEs include years of education, status of school attendance and current employment, and the 22 items in the Neurobehavioral Symptom Inventory (NSI). This phase of the project included modifying existing TBIMS variables to conform to CDE standards and adding new CDE variables previously not included in the TBIMS National Database, such as the 22 items in the NSI. Data collection forms were distributed to the Model Systems and programming was completed to allow the new CDEs to be entered into the TBIMS NDB. Twelve TBIMS Centers participated in the CDE pilot, collecting CDE data on 950 cases on either Form I at initial rehabilitation or on Form II at follow-up. CDE Pilot results were reviewed by the Project Directors (see Appendix D starting on the second page). Problems identified in the CDE pilot effort included inconsistent variable definitions and incomplete data collection instructions which resulted in inconsistencies in the CDE and TBIMS data. Inconsistent coding between CDEs and TBIMS variables resulted in an inability to crosswalk CDE and TBIMS variables for longitudinal analysis. Some CDEs added very little information or were found to be inappropriate for the TBIMS population. The pilot CDE with the strongest psychometric properties (NSI) was found to be too long for inclusion in TBIMS follow-up. For these reasons, all CDEs were rejected as additions to the TBIMS.

What opportunities for training and professional development has the project provided?

Data collectors at each of the TBIMS have been trained in consenting patients to participate in the GUID pilot, collecting the required PII, using the FITBIR GUID Tool to create GUIDs, entering those GUIDs into the TBI National Database, and the collection of all the new CDEs.

How were the results disseminated to communities of interest?

Project progress, results of comparing TBIMS and FITBIR data sharing policies, the CDE crosswalks between the TBI National Database and FITBIR, the GUID pilot process, and the CDE pilot process

were discussed with the TBIMS Project Directors at their December 2014, June and December 2015, June and December 2016, and June 2017 meetings in Arlington, Virginia. As a result of these discussions, the TBIMS Project Directors voted to adopt the GUID and transfer TBIMS data to FITBIR on an ongoing basis, but rejected adding any new CDEs to the TBIMS National Database.

What do you plan to do during the next reporting period to accomplish the goals?

This is the final report

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The impact on staff of the TBIMS NDSC and individual Centers around the country was substantial. The requirement to gain regulatory approval from both local IRBs and HRPO was complex, burdensome, and lengthy. No other TBIMS project has required a year to gain regulatory approval. Once all approvals were granted, the actual consenting and collection of the GUID and CDE pilot data were routine. The technical aspects of preparing for and transferring TBIMS data to FITBIR were complex, tedious, time consuming, and expensive. Despite quality help from FITBIR staff, the process was way more extensive than anyone had possibly imagined.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

The transfer of data from the TBIMS to FITBIR has proven far more complex than anticipated, and the loss of two staff, not easily replaced, only compounded the difficulty.

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

No significant changes in approach occurred.

Actual or anticipated problems or delays and actions or plans to resolve them

The difficulty gaining HRPO approvals and the resignation of a programmer assigned to the task of transferring the TBIMS data into FITBIR delayed the project and resulted in a request for a 1 year no cost extension of the project. The resignation of the second programmer assigned to the task of transferring the TBIMS data into FITBIR once again delayed the project and resulted in a second request for a 1 year no cost extension of the project. Without a qualified programmer with the skills and experience to transfer the TBIMS data into FITBIR, no progress on the central portion of the project could be made. More than two years were lost in twice posting, advertising, and actively recruiting for the programmer position. In the end we had to hire a consultant to successfully complete the project.

Changes that had a significant impact on expenditures

While great efforts have been made to keep project delays and the no-cost extensions from impacting total expenditures, this has only been accomplished by reassigning staff to other projects during the delays.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

6. PRODUCTS:

Publications, conference papers, and presentations

Nothing to report

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Cynthia Harrison-Felix, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0003-0489-4681
Nearest person month worked: 1 person month
Contribution to Project: Overall project management and quality assurance

Name: Gale Whiteneck, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0003-3609-5104
Nearest person month worked: 1 person month
Contribution to Project: Day to day operations of the project

Name: David Mellick
Project Role: Information Technology Project Manager
Researcher Identifier (e.g. ORCID ID): 0000-0002-2180-5575
Nearest person month worked: 4 person months
Contribution to Project: Technical management of the project

Name: Chris Cusick
Project Role: Programming Consultant
Researcher Identifier (e.g. ORCID ID): 0000-0003-4175-8451
Nearest person month worked: 3 person months
Contribution to Project: Programming for data transfer from TBIMS to FITBIR

Name: Kendra Noble
Project Role: Research Assistant
Researcher Identifier (e.g. ORCID ID): 0000-0002-2669-4894
Nearest person month worked: 4 person months
Contribution to Project: Preparation of TBIMS/FITBIR crosswalk

Name: Jennifer Coker
Project Role: IRB/HRPO Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0003-0760-7449
Nearest person month worked: 1 person month
Contribution to Project: Coordination between sites and HRPO regarding IRB and HRPO approvals.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Organization Name: Indiana University/Rehabilitation Hospital of Indiana
Location of Organization: Indianapolis, IN
Partner's contribution to the project: Collaboration

Organization Name: Moss TBI Model System
Location of Organization: Elkins Park, PA
Partner's contribution to the project: Collaboration

Organization Name: Northern New Jersey TBIMS
Location of Organization: West Orange, NY
Partner's contribution to the project: Collaboration

Organization Name: North Texas TBIMS
Location of Organization: Dallas, TX
Partner's contribution to the project: Collaboration

Organization Name: Virginia Commonwealth TBIMS
Location of Organization: Richmond, VA
Partner's contribution to the project: Collaboration

Organization Name: University of Washington TBIMS
Location of Organization: Seattle, WA
Partner's contribution to the project: Collaboration

Organization Name:	Carolinas Traumatic Brain Injury Rehabilitation and Research System
Location of Organization:	Charlotte, NC
Partner's contribution to the project:	Collaboration
Organization Name:	TIRR-Memorial Herman
Location of Organization:	Houston, TX
Partner's contribution to the project:	Collaboration
Organization Name:	Spaulding-Harvard Traumatic Brain Injury Model Systems
Location of Organization:	Boston, MA
Partner's contribution to the project:	Collaboration
Organization Name:	New York Traumatic Brain Injury Model System (Mt Sinai)
Location of Organization:	New York, NY
Partner's contribution to the project:	Collaboration
Organization Name:	Rusk Rehabilitation TBIMS at NYU
Location of Organization:	New York, NY
Partner's contribution to the project:	Collaboration
Organization Name:	University of Alabama at Birmingham Traumatic Brain Injury Model Systems
Location of Organization:	Birmingham, AL
Partner's contribution to the project:	Collaboration
Organization Name:	The Ohio Regional TBI Model System
Location of Organization:	Columbus, OH
Partner's contribution to the project:	Collaboration
Organization Name:	Mayo Clinic Traumatic Brain Injury Model System
Location of Organization:	Rochester, MN
Partner's contribution to the project:	Collaboration
Organization Name:	South Florida TBI Model System
Location of Organization:	Miami, FL
Partner's contribution to the project:	Collaboration
Organization Name:	University of Pittsburgh Medical Center Traumatic Brain Injury Model System
Location of Organization:	Pittsburgh, PA
Partner's contribution to the project:	Collaboration

8. SPECIAL REPORTING REQUIREMENTS: Not applicable

9. APPENDICES: Starting on the next page

Appendix A – Quad Chart
Appendix B – TBIMS data Submitted to FITBIR
Appendix B – SOP 602E
Appendix C – Results of Pilot Testing

Integrating Traumatic Brain Injury Model Systems Data Into the Federal Interagency Traumatic Brain Injury Research Informatics System

W81XWH-14-1-0564; 14127001

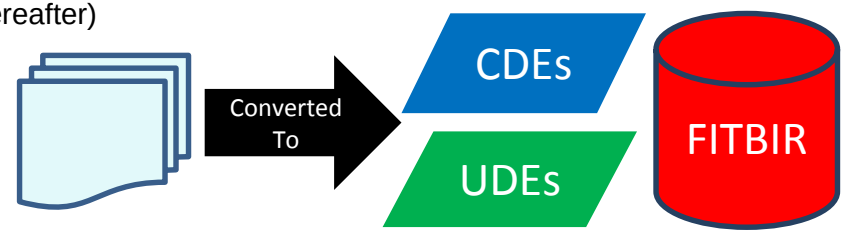
PI: Cynthia Harrison-Felix **Org:** Craig Hospital **Award Amount:** $259,100

Specific Aims: The specific aims of this proposed one year project are to evaluate:

1) the compatibility of the data sharing policies and procedures between the TBIMS and FITBIR,
2) the exact crosswalk between the TBIMS NDB and the TBI CDEs implemented by FITBIR,
3) the degree to which TBIMS variables can be converted to FITBIR CDEs, aliases, and new data elements, and these variables formatted in existing published or new FITBIR data forms,
4) the feasibility of downloading a de-identified version of the current TBIMS NDB to FITBIR,
5) the feasibility of adding the FITBIR Global Unique Identifier (GUID) over time as new and existing patients are contacted for data collection, and
6) the feasibility of prospectively collecting more CDEs that are not currently variables in the TBIMS NDB by a sample of current TBI Model Systems.

TBIMS DATA
(Initial Form Is and Follow-up Form IIs at years 1, 2, 5, 10 and every 5 years thereafter)

Converted to CDEs and UDEs and stored in FITBIR for easy access by all TBI researchers



TBIMS data converted to common data elements and unique data elements. Completed pilot testing of GUIDs and new CDEs tested in Form Is and IIs.

Timeline and Cost

Activities FY	15	16	17
Reporting			
Aim 1: Compatibility			
Aim 2: Crosswalk			
Aim 3: Conversion			
Aim 4: Download			
Aim 5: GUID			
Aim 6: CDEs			
Estimated Budget ($K)	**$259,100**	**$EWOF**	**$EWOF**

Quad Chart: 19 December 2017

Milestones:

- IRB and HRPO approvals for all sites received
- TBIMS and FITBIR data sharing policies reviewed and discussed
- Crosswalks for CDEs identified
- GUID pilot test complete
- Pilot test of addition of new CDEs complete
- TBIMS Project Directors approved transfer of data to FITBIR, but rejected the addition of new CDEs to the TBI National Database
- TBIMS data successfully transferred to FITBIR

Comments/Challenges/Issues/Concerns

- IRB and HRPO approvals took over one year and delayed data collection for those sites that took longer
- Multiple personnel changes resulted in 2 no-cost extensions
- Negotiated a 2 year delay in submission of TBIMS data to FITBIR that satisfies both NIDILRR and TBIMS Project Directors
- Inadequate detail in FITBIR CDE definitions and coding instructions

Projected Expenditure: $259,100

Actual Expenditure: $259,100

APPENDIX B
TBIMS Data Submitted to FITBIR

FITBIR Data Files	TBIMS Data Forms	Total Cases	Elements	Total Elements
FITBIR-DATA0003158	TMT_Standard-1507308280346	3,378	13	43,914
FITBIR-DATA0003157	Med_Record_Abstr_TBIMS-1507307995159	14,159	60	849,540
FITBIR-DATA0003156	DemogrFITBIR-1507305784195	14,154	137	1,939,098
FITBIR-DATA0003155	CVLTII_FITBIR-1507305213079	3,327	114	379,278
FITBIR-DATA0003154	CT_TBIMS-1507304839982	7,232	52	376,064
FITBIR-DATA0003102	TBIMS_PreInjuryHistory-1506702021492	14,156	62	877,672
FITBIR-DATA0003091	TBIMS_Form_II 2 of 2-1506619608242	20,105	76	1,527,980
FITBIR-DATA0003090	TBIMS_Form_II 1 of 2-1506618835947	20,140	76	1,530,640
FITBIR-DATA0003056	FIM_Instrument_Part2	26,670	44	1,173,480
FITBIR-DATA0003054	FIM_Instrument_Part1	29,997	44	1,319,868
FITBIR-DATA0003025	TBIQOLDepress-1506368589845	1,560	28	43,680
FITBIR-DATA0003004	TBIQOLAnxiety-1506268797822	1,552	26	40,352
FITBIR-DATA0003003	SWLS_CDISC_FITBIR-1506268275082	23,638	18	425,484
FITBIR-DATA0003002	PARTO-1506175837910	18,728	45	842,760
FITBIR-DATA0002992	OSUTBIMI-1506053676518	5,041	43	216,763
FITBIR-DATA0002991	GOSE_Standard-1506052878599	26,785	32	857,120
FITBIR-DATA0002990	DRS_TBI_FITBIR-1506051062904	27,368	17	465,256
Totals		**257,990**		**12,908,949**

APPENDIX C – SOP 602E

602e	Submission of TBIMS Data to FITBIR
Review Committee: Research	Start Date: 7/1/2017
Attachments: None	Last Revised Date:
Forms:	Last Reviewed Date:

Introduction:

The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) supports the collection of data from participants in the Traumatic Brain Injury (TBI) Model Systems Program, a collaboration of institutions across the country collecting data for research on outcomes after a TBI. The result of this collaboration is a unique well-characterized population of subjects with uniformly collected data. The TBI Model Systems Centers Program has a responsibility to the public in general, and to the scientific community in particular, to encourage scientific use of the TBI Model Systems National Database.

This document outlines the policies and procedures for submitting TBI Model System (TBIMS) data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system as one method of sharing TBIMS data with other TBI researchers. FITBIR was developed to share data across the entire TBI research field. Sharing data, methodologies, and associated tools, rather than summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches which have been developed by FITBIR.

The TBI Model Systems Centers have made a substantial long-term contribution in establishing and maintaining the National Database. NIDILRR and the TBI Model Systems encourage appropriate use of their data by other researchers. They also strongly encourage appropriate collaborative relationships between outside investigators and the TBI Model Systems investigators and they have developed longstanding procedures for external researchers requesting data directly from the TBIMS (see TBIMS Standard Operating Procedure 602d: External Use TBIMS National Database Notification). This SOP describes the commitment of the TBIMS to contribute their National Database (NDB) data to FITBIR, so that FITBIR can provide another method of facilitating access to TBIMS data by other researchers.

Purpose:

To define the process by which data in the TBI Model Systems National Database are transferred to FITBIR

Scope and Responsibilities:

The TBI National Data and Statistical Center (NDSC) implements this SOP. The TBI Model Systems Research Committee, TBI Model Systems Project Directors, and NIDILRR TBI Model Systems Centers Program Manager oversee this SOP. All TBIMS, TBIMS Follow-up Centers, NDSC, and FITBIR will abide by this procedure.

Data to be Submitted to FITBIR:

Data from the TBIMS NDB Form I (containing information through definitive discharge from inpatient rehabilitation) and Form II (containing follow-up information at 1, 2, and 5 years post injury and every 5 years thereafter) will be submitted to FITBIR. Module data will not be submitted.

Deidentification of Data:

Data submitted to FITBIR will be fully deidentified. The vast majority of TBIMS data are deidentified before entry into the TBIMS NDB stored at the TBI National Data and Statistical Center (NDSC). The NDB does not contain any names; telephone, fax, medical record, account, license, health plan, vehicle, device, or Social Security numbers; email, internet protocol, or URL addresses; or photographic, finger, or voice prints. The NDB does contain a few variables that will be deidentified before submission to FITBIR. Date of birth and date of injury will be converted to age at injury, collapsing any ages over age 89 into a single category of age 90 and over. All other dates will be converted to the number of days the date occurred after the day of injury (e.g. rehabilitation admission and discharge dates will be converted to the number of days after injury that the admission and discharge occurred; emergence from consciousness and post traumatic amnesia dates, as well as follow-up and all other dates, will be converted to days post injury. The address and zip code of residence will be converted to state of residence and the Model System that enrolled and treated the participant will be excluded from the data submitted to FITBIR.

GUID Use

When TBIMS staff recruit and consent participants, they now ask for consent to collect personal identifying information (PII) to create a Global Unique Identifier (GUID) and to submit the participant's deidentified data to FITBIR. Participants enrolled before the adoption of this practice are asked to consent at the time of their next Form II interview. The GUID Tool is a customized software application that generates a GUID for each study participant. The GUID is a subject ID that allows researchers to share data

specific to a study participant without exposing personally identifiable information (PII). The GUID allows data from an individual who participates in multiple studies to be linked in FITBIR without identifying the individual. The GUID is made up of random alpha-numeric characters and although it is generated from PII/PHI, the GUID itself does NOT contain PII/PHI. As such, it has been approved by the NIH Office of General Counsel. GUID generation complies with HIPPA regulations for the protection of PII/PHI. The process for generating a GUID involves collecting PII, entering it into the GUID Tool (a local program), and retrieving the assigned GUID. The GUID Tool combines the PII and generates three one-way hash codes. PII cannot be extracted from these hash codes, they are strictly one-way algorithms. The one-way hash codes are sent to the GUID server. If the hash codes match the server's hash codes for an existing GUID, then that GUID is returned. If the hash codes do not match, then a new random GUID is generated and returned. The GUID process has two important attributes: 1) PII is never sent to the FITBIR system and 2) The GUID is a random number that does not reveal PII/PHI. In order to generate a GUID for a subject, the following PII is required: complete legal given name of the subject at birth (first, middle if one exists, and last), date of birth, and the city and country in which subject was born. Pseudo-GUIDs are assigned if some PII is unavailable. Pseudo-GUIDs are random alpha-numeric characters that are not associated with any hash codes generated from any PII.

Cases to be Submitted

Cases will be submitted to FITBIR if they have consented to the GUID and FITBIR process. Cases will not be submitted to FITBIR if they refused GUID and FITBIR participation. Cases that have not yet been asked to participate in the GUID and FITBIR process (because they were enrolled before the GUID consenting process began and they have not yet been interviewed for their next follow-up when they will be asked) will be submitted to FITBIR with a Pseudo-GUID (a random ID not generated with PII). Cases submitted with a Pseudo-GUID are completely deidentified and they have already consented to participate in the TBIMS NDB which includes data sharing. Once they have been approached and consented, their Pseudo-GUID will be replaced by their GUID. If a case submitted under a Pseudo-GUID later refuses consent, the case will be removed from FITBIR.

Formatting of Data for Submission

The use of variables in research which have been designated as common data elements (CDEs) facilitates the advancement of TBI research and the integration of data from multiple studies. All variables in the TBIMS NDB that are CDEs or can be logically converted to CDEs will be recoded as necessary to the coding format designated by FITBIR for CDEs. Variables which cannot be converted to CDEs will be submitted to FITBIR as unique data elements (UDEs) along with uniform data dictionary information defining the coding. The conversion of TBIMS data into CDEs and UDEs and the actual transfer of data to FITBIR will be the responsibility of the National Data

and Statistical Center (NDSC). The NDSC will follow the guidelines for data formatting and transfer established by FITBIR.

Timing of Data Submission

In order to give TBIMS researchers the first opportunity to analyze and publish results from the data they have collected, there will be a two year delay in submitting TBIMS data to FITBIR, and data will only be submitted annually. When preparing data for FITBIR submission, the NDSC will use a TBIMS dataset that was archived two years ago. For example, if the NDSC prepares a data set for submission at the end of Fiscal Year 2017, they will use the TBIMS dataset archived with all data submitted by TBIMS centers to the NDSC by the end of FY2015. The next data submission to FITBIR at the end of FY2018 would be the TBIMS data that existed at the end of FY2016. TBIMS data in FITBIR would therefore be somewhere between two and nearly three years old, depending on the time of year. The two year delay in submitting data to FITBIR is intended to be consistent with the NIDILRR policy of requiring grantees to make their data public within two years of the end of a project. NIDILRR has interpreted their policy to allow up to a two year delay in sharing data from an ongoing TBI longitudinal database. The timing described above for submitting TBIMS data to FITBIR has been described by NIDILRR as the maximum delay they would allow. External researchers wishing to access more current data can continue to use the TBIMS procedures described in SOP 602d: “External Use TBIMS National Database Notification,” which has safeguards in place for not allowing external researchers to duplicate TBIMS research already underway, but provides the most current data available to approved requests.

Access to TBIMS Data in FITBIR by Other Researchers

Once TBIMS data have been submitted to FITBIR, the data are under the control of FITBIR policies and procedures. The current routine FITBIR policy is to delay access to data in FITBIR for six months after it has been submitted, before it can be accessed by other researchers also submitting data to FITBIR. For other researchers not contributing data to FITBIR, the routine delay is one year. However, FITBIR has provisions for any investigator to request early access to data in FITBIR. That request can be granted by the submitter of the data, or in rare instances, when FITBIR overrules the submitter’s denial (on the grounds that the request does not compromise completion of the ongoing study). In the case of TBIMS data in FITBIR, to remain in compliance with NIDILRR policy on data sharing, the TBIMS will routinely grant permission to investigators requesting early access. The advantage to the TBIMS of this process is that the TBIMS will learn the identity of the researcher requesting early access and the nature of the research, thereby creating an opportunity to engage the external researcher in collaboration with TBIMS researchers who have investigations or interest in the area. The option of requesting current data directly from the TBIMS under SOP 602d: “External Use TBIMS National Database Notification” also remains available to any researcher.

Encouraging Collaboration with External Researchers

Researchers requesting TBIMS data, whether directly from the TBIMS or through FITBIR, will be encouraged but not required to collaborate with TBIMS researchers. Both methods of TBIMS data access will be described on the TBIMS NDSC website and collaboration will be encouraged. The NDSC will provide FITBIR with details of the NDB to post in order to facilitate the use of TBIMS data.

References:

Standard Operating Procedure 602d: “External Use TBIMS National Database Notification”

History:

Date	Action

Review schedule:

At least every 5 years.

APPENDIX D – Results of Pilot Testing

GUID Pilot Testing

Global Unique Identifiers (GUIDs) were created using the GUID Tool and entered into the TBIMS NDB on a total of 1,689 TBIMS participants during the GUID Pilot testing. Fifteen TBIMS Centers and one Follow-up Center participated in the pilot, creating GUIDs on the following numbers of cases:

Virginia	217
TIRR	98
Ohio	176
Moss	188
UAB	56
Craig	251
Spaulding	89
Mayo	82
Kessler	37
Carolinas	23
UW	188
Pitts	47
N Texas	70
Mt Sinai	22
Indiana	110
S Florida	44
Total	**1,689**

After resolving a few procedural questions, GUID creation went smoothly with less than 7% of cases refusing to participate in the GUID and FITBIR process. Data collectors reported that people refusing the GUID process did not refuse to participate in the TBIMS data collection.

Only one aspect of the GUID pilot was problematic. Attempts to extract the personal identifying information (PII) required for GUID creation from medical records and death certificates of expired cases failed. There were seldom adequate PII available from those sources. Death certificates were not a good source of location of birth as expected.

Pilot Testing of Form I Common Data Elements

Pilot testing of six new CDEs added to Form I data collection occurred on 357 TBIMS Participants. Eighteen Data Collectors at eleven TBIMS Centers abstracted/interviewed the follow numbers of TBIMS participants:

TIRR	57
Ohio	3
Moss	49
UAB	25
Craig	17
Spaulding	89
Kessler	53
Pitts	20
N Texas	18
Mt Sinai	18
S Florida	7
Total	**357**

The six new core CDEs pilot tested on Form I were two variables that were new content being added to the NDB (TBI Type and Current Attendance at School) and four variables that represented a new coding structure for similar variables already in the NDB (Duration of LOC, Duration of PTA, Years of Education, and Current Employment Status). The results for each new CDE are presented in the order they appeared on the data collection form used in the pilot (which is included at the end).

Results of CDE TBI Type

The frequency distribution of the TBI Type CDE follows:

0.8%	Blast
82.6%	Closed
3.1%	Crush
4.5%	Penetrating
6.4%	Unknown
2.5%	Missing

While this core CDE represents new content in the TBIMS, it appears that only a small percentage of TBI cases are blast, crush, or penetrating; with closed head injury accounting for the clear majority of cases. A military population may include larger

percentages of blast, crush, or penetrating than the TBIMS civilian population. But the value of this CDE in the TBIMS is called into question when more cases are classified as unknown or missing than blast, crush, and penetrating combined.

Results of CDE Duration of Consciousness

The frequency distribution of the Duration of Consciousness CDE follows:

21.3%	None
1.4%	< 1 minute
8.7%	1-29 minutes
2.5%	30-59 minutes
13.7%	1-24 hours
16.0%	1-7 days
20.2%	> 7 days
1.7%	No return of consciousness prior to death or discharge
12.0%	Unknown
2.5%	Missing

This CDE differs from the TBIMS variable, which is calculated by subtracting the injury date from the date of first following commands to determine duration of loss of consciousness in days. As such, there is no opportunity to code LOC duration in minutes or hours. When the first date to follow commands is the same day as the injury, the TBIMS variable of Days to Follow Commands is recorded as 0.5 to indicate the time was less than 24 hours. When the first day to follow commands is one day after the Date of Injury, the Days to Follow Commands is recorded as 1, but the duration of consciousness could actually be less than 24 hours (injury in the evening with the patient first following commands the next morning). Clearly the precision of the TBIMS variable is in the longer lengths of consciousness, while the precision of the CDE is in shorter LOC. It does not make sense to replace the current TBIMS Days to Follow Commands with the CDE since a single category of LOC “>7 days” is inadequate differentiation in the TBIMS population. The question is whether it makes sense to add the CDE while retaining the TBIMS variable.

A crosstab of the CDE variable by the TBIMS revealed that many of the cases with short periods of LOC could be coded into the CDE categories. Of the 135 cases with TBIMS Days to Follow Commands of 0.5 and the 61 cases with 1 day, only 16.8% were coded as unknown or missing on the CDE Duration of LOC (36.2% were coded None, 1.5% were coded <1 minute, 14.8% coded 1-29 minutes, 3.6% coded 30-59 minutes, 23.5% coded 1-24 hours, and 3.1% coded 1-7 days). On the other hand, 11.8% of the

total sample of 356 cases had clearly inconsistent codes between the CDE and TBIMS variable (e.g. 10 days to follow commands and 1-29 minutes LOC). This inconsistency rate seems higher than data entry error and calls into question whether conflicting information appears in the record.

Results of CDE Duration of PTA

The frequency distribution of the Duration of Post-Traumatic Amnesia CDE follows:

10.4% None
0.8% < 1 minute
2.2% 1-29 minutes
0.3% 30-59 minutes
5.9% 1-24 hours
16.0% 1-7 days
45.4% > 7 days
11.8% No return of consciousness prior to death or discharge
4.8% Unknown
2.5% Missing

This CDE differs from the TBIMS variable, which is calculated by subtracting the injury date from the date of emergence from PTA to determine duration of PTA in days. As such, there is no opportunity to code PTA duration in minutes or hours. Clearly the precision of the TBIMS variable is in the longer durations of PTA, while the precision of the CDE is in shorter PTA. It does not make sense to replace the current TBIMS Days to Follow Commands with the CDE since a single category of LOC ">7 days" is inadequate differentiation in the TBIMS population. The question is whether it makes sense to add the CDE while retaining the TBIMS variable.

A crosstab of the CDE variable by the TBIMS revealed that many of the cases with short periods of PTA could be coded into the CDE categories. Of the 63 cases with TBIMS Days to Emergence From PTA of less than 2 days, only 9.5% were coded as unknown or missing on the CDE Duration of PTA (42.9% were coded None, 3.2% were coded <1 minute, 6.3% coded 1-29 minutes, 1.6% coded 30-59 minutes, 28.6% coded 1-24 hours, and 4.8% coded 1-7 days). On the other hand, 6.7% of the total sample of 356 cases had clearly inconsistent codes between the CDE and TBIMS variable (e.g. 12 days to emerge from PTA and 1-29 minutes PTA). This inconsistency rate seems higher than data entry error and calls into question whether conflicting information appears in the record.

Results of CDE Years of Education at Injury

The frequency distribution of the number of years of education completed follows:

Years	Percent of Cases
2	0.3%
3	0.3%
5	0.3%
6	0.6%
8	3.1%
9	3.6%
10	5.0%
11	8.1%
12	28.9%
13	7.6%
14	7.8%
15	4.8%
16	12.3%
17	1.1%
18	6.4%
19	1.1%
20	3.6%
21	0.3%
Unknown	2.5%
Missing	2.2%

This CDE variable differs slightly from the current TBIMS Years of Education which focuses on working toward and obtaining specific degrees beyond high school. The codes in the current TBIMS Years of Education are identical up through 10 years of education, but then differ as follows:

11	11 or 12 Years: No Diploma
12	HS Diploma
13	Work Toward Associate's Degree
14	Associate's Degree
15	Work Toward Bachelor's Degree
16	Bachelor's Degree
17	Work Toward Master's Degree
18	Master's Degree
19	Work Toward Doctoral Level Degree

20 Doctoral Level Degree
66 Variable Did Not Exist
77 Other
99 Unknown

The two variables are not as far apart as they would appear. Instructions for the CDE state:

> "For years completed, after the age of 5, code the number of years attained (0-30 years), normed to someone moving full time at the usual pace, i.e. a year that was repeated counts as only 1 year and the usual single-year full-time load completed over several years counts as 1 year. Certificate and technical programs do NOT count no matter how specialized. The number of years of typical completion of the relevant program is counted. If the subject obtained their education outside the United States, ask about their educational system to estimate the correct coding - Internship, Residency, and Fellowship years are experiential training and do not count."

Since the CDE instructions state that the number of years of typical completion of the relevant program is counted, the codes for degrees in the TBIMS variable match the typical number of years required to complete the degree. The odd number codes corresponding to "working toward degrees" also seem appropriate.

In a crosstab between the CDE and the current TBIMS variable, there was some inconsistency between the variables in terms of missing data. The TBIMS variable had 1.4% unknown or missing data while the CDE had 4.8% (with 5.3% unknown or missing on one or both measures). Beyond those differences, the remaining cases with valid data on both measures were extremely consistent with 92.3% having identical values and 5.3% only differing by one year of education. Only one case was more inconsistent than a difference of 2 years (the CDE coded as 16 years and a TBIMS value of a high school diploma, which could be a data entry error or a person attending college for 4 full years without graduating.

This CDE could replace the current TBIMS variable if a computed variable that collapsed education beyond high school into two categories of "some college" and "some graduate school" were deemed acceptable as a crosswalk.

<u>Results of CDE Current School Attendance Status at Injury</u>

The frequency distribution of the CDE current school attendance status at injury is listed below:

5.9%	Going to school
0.6%	On vacation from school (between grades)
91.3%	Neither (not currently in school)
2.2%	Missing

While this core CDE represents new content in the TBIMS, it appears relevant to a very small percentage of TBIMS cases. While adding this variable would increases the number of core TBI CDEs included in the NDB, the importance of this variable seems to be on the decline, particularly for a primarily adult population.

Results of CDE Current Employment Status at Injury

The frequency distribution of the current employment status follows:

44.5%	Working full time: 35 hrs or more/week, at least minimum wage
5.0%	Working 20-34 hrs/week, at least minimum wage
1.7%	Working less than 20 hrs/week, at least minimum wage
0.6%	Temporary/odd jobs/less than minimum wage
0.3%	Special employment: sheltered workshop/supportive employ/job coach
0.3%	Sick or maternity leave
35.9%	Not in paid workforce: child/retired/student/homemaker/disabled pre-injury
4.8%	Unemployed
0.8%	Other
0.3%	Unknown
2.2%	Missing

This CDE variable differs from the current TBIMS Primary Employment Status because it differentiates four categories of competitive employment (based on hours worked, temporary/odd jobs, and wage) but combines several TBIMS employment categories into “not in paid workforce.”

The codes for the TBIMS variable follow:

2	Full time student
3	Part time student
4	Special student / other non-regular education
5	Competitive employment

7 Taking care of house or family
8 Special employment
9 Retired: age-related
10 Unemployed: looking
11 Volunteer work
12 Retired: disability
13 Unemployed: not looking
14 Hospitalized without pay
15 Retired: other
16 On leave from work: not receiving pay
17 Medical leave with pay or workers comp
55 Other
66 Variable did not exist
77 Refused
99 Unknown

While the coding structure is quite different between the CDE and the TBIMS variable, the majority of the data were logically consistent in a crosstab between the two variables. There was a slight mismatch with 1.1% missing data in the TBIMS variable and 2.5% missing in the CDE. No pairs of valid codes were clearly inconsistent, but 2.9% were suspicious.

Adding categories to the current TBIMS employment variable (like temporary/odd jobs, subminimum wage jobs, and on maternity leave with pay) and using the TBIMS employment hours variable to distinguish among competitive employment categories could allow a crosswalk to this CDE employment status variable and still maintain consistency with the TBIMS computed employment variable. The coding structure for the current TBIMS computed employment variable is somewhat simpler with the following codes:

2 Full time student
3 Part time student
4 Special education
5 Employed competitively
7 Homemaker
8 Special employment
9 Retired
10 Unemployed
11 Volunteer work
77 Other

88 Not applicable
99 Unknown

Pilot Testing of Form II Common Data Elements

Pilot testing of four new CDEs added to Form II data collection occurred on 569 TBIMS participants: 139 at Year 1, 139 at Year 2, 126 at Year 5, 115 at Year 10, 75 at Year 15, 1 at Year 20, and 1 at Year 25. Seventeen Data Collectors at ten TBIMS Centers and one Follow-up Center interviewed the following numbers of TBIMS participants:

TIRR	21
Ohio	19
Moss	103
UAB	84
Craig	184
Spaulding	18
Carolinas	63
Pitts	4
N Texas	74
Mt Sinai	18
S Florida	10
Total	**596**

The four new core CDEs pilot tested on Form II were two variables that were new content being added to the NDB (Current Attendance at School and the 22-item Neurobehavioral Symptom Inventory) and two variables that represented a new coding structure for similar variables already in the NDB (Years of Education and Current Employment Status). The results for each new CDE are presented in the order they appeared on the data collection form used in the pilot (which is included at the end).

Results of CDE Years of Education at Folllow-up

The frequency distribution of the number of years of education completed follows:

Years	Percent of Cases
5	0.2%
6	0.5%
7	0.7%
8	0.8%
9	1.5%

10	3.0%
11	9.6%
12	27.3%
13	9.7%
14	11.1%
15	9.1%
16	13.6%
17	3.5%
18	4.7%
19	1.0%
20	0.7%
21	0.3%
28	0.2%
Unknown	0.4%
Missing	1.8%

This CDE variable differs slightly from the current TBIMS Years of Education which focuses on working toward and obtaining specific degrees beyond high school. The codes in the current TBIMS Years of Education are identical up through 10 years of education, but then differ as follows:

11	11 or 12 Years: No Diploma
12	HS Diploma
13	Work Toward Associate's Degree
14	Associate's Degree
15	Work Toward Bachelor's Degree
16	Bachelor's Degree
17	Work Toward Master's Degree
18	Master's Degree
19	Work Toward Doctoral Level Degree
20	Doctoral Level Degree
66	Variable Did Not Exist
77	Other
99	Unknown

The two variables are not as far apart as they would appear. Instructions for the CDE state:

> "For years completed, after the age of 5, code the number of years attained (0-30 years), normed to someone moving full time at the usual pace, i.e. a year that

was repeated counts as only 1 year and the usual single-year full-time load completed over several years counts as 1 year. Certificate and technical programs do NOT count no matter how specialized. The number of years of typical completion of the relevant program is counted. If the subject obtained their education outside the United States, ask about their educational system to estimate the correct coding - Internship, Residency, and Fellowship years are experiential training and do not count."

Since the CDE instructions state that the number of years of typical completion of the relevant program is counted, the codes for degrees in the TBIMS variable match the typical number of years required to complete the degree. The odd number codes corresponding to "working toward degrees" also seem appropriate.

In a crosstab between the CDE and the current TBIMS variable, the vast majority of cases were quite consistent between the two coding structures. Only 0.8% were clearly inconsistent and 0.5% were suspicious. These differences may simply be data entry errors.

This CDE could replace the current TBIMS variable if a computed variable that collapsed education beyond high school into two categories of "some college" and "some graduate school" were deemed acceptable.

Results of CDE Current School Attendance Status at Follow-up

The frequency distribution of the current school attendance status follows:

8.6%	Going to school
1.3%	On vacation from school (between grades)
87.8%	Neither (not currently in school)
0.7%	Unknown
1.7%	Missing

While this core CDE represents new content in the TBIMS, it appears relevant to a very small percentage of TBIMS cases. While adding this variable would increases the number of core TBI CDEs included in the NDB, the importance of this variable seems to be on the decline, particularly for a primarily adult population.

Results of CDE Current Employment Status at Follow-up

The frequency distribution of the current employment status follows:

28.2%	Working full time: 35 hrs or more/week, at least minimum wage
7.0%	Working 20-34 hrs/week, at least minimum wage
3.5%	Working less than 20 hrs/week, at least minimum wage
0.2%	Temporary/odd jobs/less than minimum wage
0.7%	Special employment: sheltered workshop/supportive employ/job coach
0.3%	Sick or maternity leave
32.4%	Not in paid workforce: child/retired/student/homemaker/disabled pre-injury
24.3%	Unemployed
1.0%	Other
0.5%	Unknown
1.8%	Missing

This CDE variable differs from the current TBIMS Primary Employment Status because it differentiates four categories of competitive employment (based on hours worked, temporary/odd jobs, and wage) but combines several TBIMS employment categories into “not in paid workforce.”

The codes for the TBIMS variable follow:

2	Full time student
3	Part time student
4	Special student / other non-regular education
5	Competitive employment
7	Taking care of house or family
8	Special employment
9	Retired: age-related
10	Unemployed: looking
11	Volunteer work
12	Retired: disability
13	Unemployed: not looking
14	Hospitalized without pay
15	Retired: other
16	On leave from work: not receiving pay
17	Medical leave with pay or workers comp
55	Other
66	Variable did not exist
77	Refused
99	Unknown

While the coding structure is quite different between the CDE and the TBIMS variable, the majority of the coding was logically consistent in a crosstab between the two variables. However there was confusion between retired and unemployed on Form II vs not in the workforce and unemployed on the CDE. In 11.6% of the cases, retired was coded on Form II while unemployed was coded on the CDE (when "not in workforce" should have been coded). In 2.7% of the cases, unemployed was coded on Form II while not in workforce was coded on the CDE (when unemployed should have been coded).

Adding categories to the current TBIMS employment variable (like temporary/odd jobs, subminimum wage jobs, and on maternity leave with pay) and using the TBIMS employment hours variable to distinguish among competitive employment categories could allow a crosswalk to this CDE employment status variable and still maintain consistency with the TBIMS computed employment variable. The coding structure for the current TBIMS computed employment variable is somewhat simpler with the following codes:

2	Full time student
3	Part time student
4	Special education
5	Employed competitively
7	Homemaker
8	Special employment
9	Retired
10	Unemployed
11	Volunteer work
77	Other
88	Not applicable
99	Unknown

Results of CDE Neurobehavioral Symptom Inventory

Complete data on all 22 items of the Neurobehavioral Symptom Inventory (NSI) were collected from 557 cases during the CDE Form II Pilot test. Total NSI scores and four NSI subscale factor scores (Somatosensory, Affective, Cognitive, and Vestibular) were calculated, as well mean item values for the total and subscale scores so they could be displayed on similar graphs which appear on the next page.

Adding this variable would increase the number of core TBI CDEs included in the NDB and it quantifies postconcussive symptoms. This is a concept not currently measured in the TBIMS NDB, but some of the symptoms are assessed in other measures like depression and anxiety. The NSI has been used extensively in the VA and it is included in the VA PRC Database which mirrors most of the TBIMS variables. While collecting responses to NSI items goes quickly, there are 22 items to assess.

The NSI data collected in this pilot could be compared with NSI data collected in the VA PRC Database to determine the relative magnitude of postconcussive symptoms in civilian and veteran settings. The relations between postconcussive symptoms and other measures of TBI severity, as well as outcomes, could also be examined in the pilot sample without adding this instrument to the TBIMS NDB. The results of these investigations could shed light on the relative importance of adding the NSI to the NDB.

Form I and Form II Pilot CDE Data Collection Forms

The forms used to collect the new CDEs added to Form I and Form II appear on the next pages.

Form I Common Data Elements for FITBIR Pilot

KEYS **Subject ID**

TBITYP **Type of TBI**

1 – Blast
2 – Closed
3 – Crush
4 – Penetrating
9 – Unknown

LOCDUR RANG **Duration of LOC** Code first indication found in the record of the patient following commands

0 – None (No LOC)
1 – <1 Minute
2 – 1-29 Minutes
3 – 30-59 Minutes
4 – 1-24 Hours
5 – 1-7 Days
6 – >7 Days
7 – No Return Of Consciousness Prior To Death Or Discharge
99 – Unknown

PSTTRAUMAMNSDUR RANG **Duration of Post-Traumatic Amnesia** Code first indication found in the record of the patient emerging from PTA

0 – None (No PTA)
1 – <1 Minute
2 – 1-29 Minutes
3 – 30-59 Minutes
4 – 1-24 Hours;
5 – 1-7 Days
6 – >7 Days
7 – No Emergence From PTA Prior To Death Or Discharge
88 – NA
99 – Unknown

EDUYRCT **How many years of education does the subject have?**

77 – Refused; **99** - Unknown

EDUSCHOOLPARTICIPSTATUS **Status of the participant's current attendance at school**

1 – Going To School
2 – On Vacation From School (Between Grades)
3 – Neither (Not Currently In School)
99 – Unknown

EMPLMTEXPNDSTATUS **Status of participant's current employment**

If other, please specify

1 – Working Full Time (35 Hrs Or More/Week, At Least Minimum Wage)
2 – Working 20-34 Hrs/Week, At Least Minimum Wage
3 – Working Less Than 20 Hrs /Week, At Least Minimum Wage
4 – Temporary/Odd Jobs/Less Than Minimum Wage Jobs
5 – Special Employment (Sheltered Workshop, Supportive Employment, Job Coach
6 – Sick Or Maternity Leave
7 – Not In Paid Workforce (Including Child, Retired, Student, Homemaker, Disabled Pre-Injury)
8 – Unemployed
9 – Unable To Obtain Information
77 – Other, Specify
99 – Unknown

Did you have any issues collecting or entering this data?

KEYS

Subject ID:

Follow-Up Period:

EDUYRCT

How many years of education do you have?

77 - Refused; **99** - Unknown

EDUSCHOOLPARTICIPSTATUS

What is the status of your current attendance at school?

1 – Going To School
2 – On Vacation From School (Between Grades)
3 – Neither (Not Currently In School)
99 – Unknown

EMPLMTEXPNDSTATUS

What is the status of your current employment?

If other, please specify

1 – Working Full Time (35 Hrs Or More/Week, At Least Minimum Wage)
2 – Working 20-34 Hrs/Week, At Least Minimum Wage
3 – Working Less Than 20 Hrs /Week, At Least Minimum Wage
4 – Temporary/Odd Jobs/Less Than Minimum Wage Jobs
5 – Special Employment (Sheltered Workshop, Supportive Employment, Job Coach
6 – Sick Or Maternity Leave
7 – Not In Paid Workforce (Including Child, Retired, Student, Homemaker, Disabled Pre-Injury)
8 – Unemployed
9 – Unable To Obtain Information
77 – Other, Specify
99 – Unknown

Neurobehavioral Symptom Inventory (NSI) Data Collection Form

Please rate the following symptoms with regard to how much they have disturbed you <u>in the past two weeks</u>…

NSI **Visit Date** ☐☐ / ☐☐ / ☐☐☐☐

07/07/7777 - Patient Unable To Complete; **08/08/8888** - Not Applicable; **09/09/9999** - Unknown

1.	**Feeling dizzy:**	☐
2.	**Loss of balance:**	☐
3.	**Poor coordination, clumsy:**	☐
4.	**Headaches:**	☐
5.	**Nausea:**	☐
6.	**Vision problems, blurring, trouble seeing:**	☐
7.	**Sensitivity to light:**	☐
8.	**Hearing difficulty:**	☐
9.	**Sensitivity to noise:**	☐
10.	**Numbness or tingling on parts of my body:**	☐
11.	**Change in taste and/or smell:**	☐
12.	**Loss of appetite or increased appetite:**	☐
13.	**Poor concentration, can't pay attention, easily distracted:**	☐
14.	**Forgetfulness, can't remember things:**	☐
15.	**Difficulty making decisions:**	☐
16.	**Slowed thinking, difficulty getting organized, can't finish things:**	☐
17.	**Fatigue, loss of energy, getting tired easily:**	☐
18.	**Difficulty falling or staying asleep:**	☐
19.	**Feeling anxious or tense:**	☐
20.	**Feeling depressed or sad:**	☐
21.	**Irritability, easily annoyed:**	☐
22.	**Poor frustration tolerance, feeling easily overwhelmed by things:**	☐

0 - **NONE** (Rarely if ever present, not a problem at all);
1 - **MILD** (Occasionally present, but it does not disrupt activities; I can usually continue what I'm doing; doesn't really concern me);
2 - **MODERATE** (Often present, occasionally disrupts activities; I can usually continue what I'm doing with some effort; I feel somewhat concerned);
3 - **SEVERE** (Frequently present and disrupts activities; I can only do things that are fairly simply or take little effort; I feel like I need help);
4 - **VERY SEVERE** (Almost always present and I have been unable to perform at work, school, or home due to this problem; I probably cannot function without help);
7 - Patient Unable To Complete;
9 - Unknown

Did you have any issues collecting or entering this data?